

Notice of Allowability

| Application No. | Applicant(s) |
|-------------------|---------------|
| 09/557,907 | HORTON ET AL. |
| Examiner | Art Unit |
| Michael C. Wilson | 1632 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address--*

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to 2-27-04.
2. The allowed claim(s) is/are 1,3-7,16-18,30-35,38-41,43,46-50,66,69,71-74,77,78 and 83-86.
3. The drawings filed on 21 April 2000 are accepted by the Examiner.
4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of the:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) including changes required by the Notice of Draftperson's Patent Drawing Review (PTO-948) attached
 1) hereto or 2) to Paper No./Mail Date _____.
(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of
 Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. Notice of References Cited (PTO-892)
2. Notice of Draftperson's Patent Drawing Review (PTO-948)
3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
 Paper No./Mail Date _____
4. Examiner's Comment Regarding Requirement for Deposit
 of Biological Material
5. Notice of Informal Patent Application (PTO-152)
6. Interview Summary (PTO-413),
 Paper No./Mail Date _____
7. Examiner's Amendment/Comment
8. Examiner's Statement of Reasons for Allowance
9. Other _____.

MICHAEL WILSON
PRIMARY EXAMINER



REASONS FOR ALLOWANCE

Continued Prosecution Application

The request filed on 2-27-04 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/557907 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 remain pending.

Specification

The amendments to the abstract and the title have been entered.

Claim Objections

The objections to the claims have been withdrawn in view of the amendments.

The following is an examiner's statement of reasons for allowance:

Claim Rejections - 35 USC § 112

The rejection of claims 16 and 18 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of the amendments to claims 16 and 18 making them dependent upon claim 1.

Double Patenting

The rejection of claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 164, 185, 189, 201, 202, 206, 207, 209, 210, 212, and 213 of copending Application No. 09/839574 in view of Dalgleish (1995, Cancer

Surveys, Vol. 296, pg 289-320) has been withdrawn because the claims of '574 are directed toward a method of delivering a polynucleotide using a salt "M-X" and a poloxamer or reverse poloxamer.

The rejection of claims 1, 3-6, 16-18, 30-35, 38-41, 43 and 46-50 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48, 52, 57, 59, 61, 72, 74, 76, 77, 79, 81, 82 and 84 of copending Application No. 09/588655 in view of Dalgleish (1995, Cancer Surveys, Vol. 296, pg 289-320) has been withdrawn. The claims of '655 are limited to administering a polynucleotide free from association with liposomal formulations, charged lipids, transfection-facilitating precipitating agents, and transfection-facilitating viral particles to the heart cells of a vertebrate heart. It is not readily apparent that administering polynucleotides to the heart as in '655 can be used to treat cancer or metastasis as claimed in the instant application.

The rejection of claims 1, 3-7, 16-18, 30-35, 38-41, 43, 46-50, 66, 69, 71-74, 77, 78 and 83-86 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/028782 has been withdrawn because the claims of 10/028782 are distinct from the instant claims because the claims of '782 are limited to delivering RNA while the instant claims are limited to delivering DNA. Applicants' argument is not persuasive. The claims of '782 encompass administering any polynucleotide that directs synthesis of a therapeutic protein. Dependent claim 122 is specifically limited to DNA.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER